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09/744,675	01/29/2001	Edward L. Squires	XY-EQUINE3-U	3456
33549 7590 10/02/2007 SANTANGELO LAW OFFICES, P.C. 125 SOUTH HOWES, THIRD FLOOR FORT COLLINS, CO 80521			EXAMINER MYERS, CARLA J	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/744,675

Applicant(s)

SQUIRES ET AL.

Examiner

Carla Myers

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 138-145 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 138-145 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 30, 2007 has been entered.

2. Applicant's arguments and amendments set forth in the response of July 30, 2007 have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. In particular, the rejection under 35 USC 103 over Seidel (U.S. Patent No. 6,149,867), Wilhelm and Rath in view of the showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a).

This action contains new grounds of rejection necessitated by Applicant's amendments to the claims and is made non-final.

3. Claims 138-145 are pending and have been examined herein.

New Grounds of Rejection

Claim Rejections - 35 USC § 112 – New Matter

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 138-145 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification as originally filed does not appear to provide support for the claimed methods of establishing an equine artificial insemination sample containing at least some sperm that are capable of fertilizing at least one egg within a female equine "at success levels not statistically different as compared to an unsorted equine artificial insemination dosage containing about the same number of sperm cells." Original claim 5 provides support for the concept of the use of a sorted sperm sample containing a "low" number of sperm, as defined by claim 4, and achieving fertilization rates that are statistically comparable to the typical artificial insemination dosage. However, the present claims are not limited to this subject matter. In particular, the present claims do not recite a comparison of fertilization levels between a low dosage sorted sperm sample, as defined by originally filed claim 4 and an unsorted equine artificial insemination sample. Even if the claims did recite this limitation, there does not appear to be proper antecedent basis for this limitation in the specification. The specification (-page 39) also teaches a comparison of the fertilization results obtained with 25×10^6 sorted sperm versus non-sorted sperm. It was determined that under the specific conditions of that assay, the differences in fertilization rates (40% vs 57%) were not "statistically significant." However, in this example, the two samples that are compared

had the same number of sperm cells. Further, the present claims are not limited to the specific conditions under which these results were obtained. There is no general statement set forth in the specification to provide support for the broader concept of performing the claimed method in order to achieve fertilization success rates not statistically different as compared to an unsorted equine artificial insemination dosage containing about the same number of sperm cells."

Response to remarks:

In the response, Applicants state that the term "about" is used in the art to describe the number of sperm cells used in artificial insemination procedures and cites several publications which use the term "about" with respect to the number of sperm cells. Applicants further state that the term "at least" is not new matter. These arguments have been fully considered but are not persuasive. The rejection is not based on the fact that the terms "at least" or "about" are new terms not previously used in the art. The rejection is based on the finding that the present specification does not appear to provide support for the concept set forth in the claims of a method of equine artificial insemination in which a sorted sperm sample is used to obtain fertilization success levels "not statistically different as compared to an unsorted equine artificial insemination dosage containing about the same number of sperm cells." The response does not point to any particular teachings in the present specification as providing support for this limitation.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 138-140, and 142-145 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rens (U.S. Patent No. 5,985,216) in view of Wilhelm (Cryobiology (1996) 33:320-329) and further in view of Rath (Theriogenology. April 1997, 795-800; cited in the IDS) .

Rens teaches a method of sex-sorting sperm using high speed flow cytometry. In the method of Rens (see columns 4-6), a sample of sperm is obtained from a male mammal, the sperm is stained with Hoechst 33342 dye in order to distinguish between

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viable and nonviable sperm (column 5, lines 4-10), the sperm are sorted in a high speed flow cytometer using a nozzle that forms a stable droplet containing each individual sperm cell (column 2, lines 23-32), the sperm are sorted according to their sex characteristics and isolated populations of X- and Y-chromosome bearing sperm are collected. Importantly, Rens (col. 5) discloses modifying the MoFlo® high speed cell sorter to include a new elliptical nozzle capable of more accurately orienting sperm for accurate sorting. Rens teaches use of the modified MoFlo® sorter using sampling rates of 500 sperm/second and 2000 sperm/second (column 6). Further, Rens teaches that the modified MoFlo® sorter also allowed for sample rates up to at least 15,000 sperm/sec (column 4, lines 29-31). Rens (col. 2) teaches that the high speed flow cytometry apparatus disclosed therein provides for improved accuracy and efficiency of sorting, as compared to prior art flow cytometers. Rens (col. 2) also teaches that it is desirable to use high speed cell sorters to maximize the number of sorted sperm per unit time. For example, Rens (col. 4) discuss the requirement to use large quantities of sperm for artificial insemination and states that by using the high speed cell sorter equipped with the nozzle disclosed therein, the yield of sex sorted sperm cells can be increased at least 10 fold, making artificial insemination with sexed semen a more feasible option. Rens (col. 7) also exemplifies a method wherein a total of 50 million X and Y bovine sperm were sorted in a 7 hour period using the modified MoFlo® sorter equipped with the new elliptical nozzle. Rens also exemplifies using the sorting method to sex-sort rabbit, bull, mouse and human sperm (columns 4-7) and states that the

sorting method can be used with any mammalian sperm (column 4, lines 38-42). Rens does not specifically teach applying the sorting method to equine sperm.

However, Wilhelm (page 321) teaches the use of equine sperm for the purpose of artificial insemination and teaches methods for the effective cryopreservation of equine sperm. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have applied the method of Rens to the sorting of equine sperm in order to have provided an effective means for distinguishing between and collecting populations of X- and Y-chromosome bearing sperm useful for artificially inseminating equine.

Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the used the modified MoFlo sorter equipped with the new nozzle to sort equine sperm at very high sort rates, including sorting rates that result in the collection of 900 viable sperm / second, in order to have allowed for the faster sorting of sperm so as to have provided adequate quantities of sex-sorted samples that could be used for the insemination process. As discussed in MPEP 2144.05(b), "(w)here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955). Further, It is well settled that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." *In re Boesch*, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980). See also *Merck & Co. v. Biocraft Labs. Inc.*, 874 F.2d 804, 809, 10 USPQ2d 1843, 1847-48 (Fed. Cir. 1989) (determination of suitable dosage amounts in

diuretic compositions considered a matter of routine experimentation and therefore obvious). In the present situation, Rens provides the motivation to increase sort speeds to at least that required to achieve the collection of 900 viable sperm/sec and the means for achieving this result (i.e., the modified MoFlo® high speed sorter including the elliptical nozzle of Rens). Thereby, modification of the method of Rens so as to have sorted equine sperm at rates that achieve the collection of 900 viable sperm/second would have been obvious to one of ordinary skill in the art and well within the skill of the art at the time the invention was made.

Secondly, Rens does not specify the solution into which the sperm cells are collected and thereby does not teach collecting the sorted sperm in a skim milk solution. However, Rath (page 796) teaches collecting sex-sorted sperm into a collection media composed of TEST extender containing 2% hen egg yolk. Thus, Rath teaches the concept of collecting sperm sorted cells into a sperm extender medium. Wilhelm teaches extending equine sperm in skim milk solution containing 2% egg yolk by volume (page 322; referred to therein as SMEY). Additionally, Wilhelm teaches that SMEY extender effectively preserves equine sperm during freezing and thawing and teaches that egg yolk and skim milk may contain components which protect spermatozoa membranes (page 326).

Accordingly, in view of the teachings of Rath and Wilhelm, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have further modified the method of Rens so as to have collected the equine sperm in the SMEY extender solution of skim milk and egg yolk in order to have sorted the sperm

into a medium that helped to preserve the sperm and/or which could be used for subsequently freezing and then thawing the sorted equine sperm. Specifically, Rath teaches that the sorted sperm are collected into a tube containing sperm extender and it would have been obvious to the ordinary artisan that alternative extenders that were known in art to be effective for preserving equine sperm, such as the skim milk extender of Wilhelm, could be present in the collection tube in order to ensure the proper collection of the sperm.

Regarding the recitation in the claims at step (j), it is considered to be a property of the artificial insemination sample that is obtained using the modified method of Rens in which the equine sperm is collected into a media containing egg yolk and skim milk that the sample contains sperm cells that are capable of fertilizing at least one equine egg at a level not statistically different from that obtained using a typical unsorted equine artificial insemination dosage.

With respect to claim 140, the recitation of "about four percent egg yolk" is considered to encompass 2% egg yolk. Furthermore, it would have been well within the skill of the art at the time the invention was made to have modified the concentration of egg yolk in the extender solution in order to have provided the most effective concentration of egg yolk depending on the other reagents present in the extender solution.

With respect to claim 143, Rens does not specify the pressure used to operate the high speed cell sorter. However, methods for sorting equine sperm using high speed cell sorters were well known in the art at the time the invention was made. To

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determine the optimum conditions for performing the sorting of sperm, including the sorting rates and pressure of the cell sorter is considered to be well within the skill of the art. As discussed in MPEP 2144.05(b), "(w)here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

With respect to claims 144 and 145, Rens teaches that 4 to 5 million sorted sperm were used to inseminate dairy cows, but does not teach the quantity and volume of sperm to be used in equine artificial insemination samples. Additionally, Rath (page 796) teaches the use of 0.2 million sorted porcine spermatozoa per oviduct and teaches resuspending sorted porcine sperm in a solution having a volume of 0.2 ml. Rath teaches that approximately 3.5 to 4×10^5 sperm cells were sorted into each tube. Since the parameters which effect artificial insemination of equine were known in the art at the time the invention was made, it would have been obvious to one of ordinary skill in the art and well within the skill of the art to have selected an optimum quantity of sperm, wherein said quantity would be less than 25 million and to have selected the optimum volume for the artificial insemination sample, so as to have provided the most effective sample for inseminating equine while keeping the number of sperm to be used for insemination at the lowest possible number given the constraints on how many sperm could be sorted per day and the cost of sorting. Additionally, the ordinary artisan would have recognized that the quantity of sperm and the volume of the sperm sample could be modified in order to have provided the most appropriate sperm sample depending on

how the sample would be used – i.e., depending on the amount of sperm present in the original sample, whether the samples would be frozen prior to use, the number of samples to be used for insemination, and the type of insemination technique.

Accordingly, to have generated sorted sperm samples containing less than 5 or 25 million sperm or to have generated sorted sperm samples in a volume of .2 or 1 ml would have been obvious to one of ordinary skill in the art because the ordinary artisan would have recognized that the quantity of sperm and the volume of sample should be varied depending on how the sperm sample was to be further processed and / or used.

RESPONSE TO ARGUMENTS:

In the response, Applicants traversed the rejection by stating that Rens does not disclose any data showing the achievement of Applicant's claimed sort rates. Applicants point to the Rens 1999 publication as showing that a cell sorter equipped with an elliptical nozzle provided sampling rates of 2000 sperm/second, resulting in sort rates of 200 sperm /second. It is argued that these sort rates are below those presently claimed. Applicants assert that the Office has not provided any evidence to establish that the Rens '216 patent achieved sort rates of 900 sorts/second. Applicants state that the prior Office action indicated that "it is incumbent on the Applicant to provide various kinds of declarations and evidences." Applicants assert that they are under no obligation to provide evidence of nonobviousness.

These arguments have been fully considered but are not persuasive. First, it is noted that the Office did not require Applicant to provide declaratory evidence. The prior

Office action stated only that Applicants had not provided any type of evidence to support their allegations regarding the Rens '216 patent.

With respect to the Rens 1999 reference (Molecular Reproduction and Development 52: 50-56), the data disclosed therein was obtained using an EPICS 750 series flow cytometer equipped with an elliptical nozzle. In addition to Applicant's characterization of this reference, Rens (1999) also teaches that sampling rates of 3,000 to 4,000 have been achieved and that these sampling rates provide equally effective results as that obtained with sampling rates of 500 sperm/second (page 53). Rens (1999) also notes that the new elliptical nozzle has been fitted onto the MoFlo® high speed cell sorter and "even greater increases in sorting efficiency" have been achieved (page 55). It is this modified MoFlo® high speed sorter equipped with an elliptical nozzle that is disclosed in the Rens '216 patent, over which the present claims have been rejected (see, e.g., col. 5 of the '216 Rens patent). Rens (1999) does not state the particular sorting rates achieved with the modified MoFlo® sorter. However, Rens (Animal Reproduction Science. 2000. 60 : 93-107 ; cited in the IDS) does discuss the improved sorting results obtained with the modified MoFlo® sorter equipped with the elliptical nozzle. In particular, Rens (2000; page 98), teaches that this modified device has the capacity to sort at rates of 50,000 events/second, as compared to the standard rate of 5,000 to 10,000 events/ second. Rens (2000; abstract) teaches that this modified MoFlo® sorter with an elliptical nozzle (i.e., the device disclosed by Rens '216) allows for the sorting of X-bearing sperm at a rate of about 18 million sperm / hour – i.e., 5000 sperm/sec.

Accordingly, given the analogy set forth by Applicants with respect to the Rens (1999) reference, if a sampling rate of 2000 sperm / second results in a sort rate of 200 sperm/second, then the sampling rate of 15,000 disclosed by the Rens '216 patent should achieve sort rates of 1,500 sperm/sec (see col. 4, lines 29-31 of '216). Thereby, in the absence of evidence to the contrary, it is maintained that such sampling rates would allow for sorting rates of at least 900 sorts/second.

Further, even if Rens does not specifically exemplify a method in which sort rates of 900 sorts/sec are achieved, Rens provides the motivation to use the modified MoFlo® flow cytometer to achieve the sorting and collection rate of at least 900 sperm / sec because Rens specifically teaches the need to obtain large quantities of sorted sperm in a short period of time to allow for successful artificial insemination of mammals with sorted sperm (col. 4, lines 43-49; col. 5, lines 46-57).

Applicants are reminded that that the present rejection is made under 35 USC 103, and not under 35 USC 102. Obviousness does not require absolute predictability but only the reasonable expectation of success. See In re Merck and Company Inc., 800 F. 2d 1091, 231 USPQ 375 (Fed. Cir. 1986) and In re O'Farrell, 7 USPQ2d 1673 (Fed. Cir. 1988).

Additionally, as stated in *Ex parte Kubin* (No. 2007-0819, Bd. Pat. App. & Int. May 31, 2007): "Under *KSR*, it is now apparent "obvious to try" may be an appropriate test in more situations than we previously contemplated. When there is motivation to solve a problem and there are a finite number of identified predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of

innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under 103. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct 1727, 82 USPQ2d 1385, 1397 (2007)." This reasoning is also applicable to the present situation wherein the prior art of Rens provides both the motivation to increase the rate of sorting and collecting sperm and the means (i.e., the modified MoFlo® sorter equipped with the elliptical nozzle) to achieve the result of sorting and collection rates of about 900 sperm/sec.

6. Claim 141 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rens in view of Wilhelm and Rath and further in view of Catt (cited in the IDS of January 29, 2001).

The teachings of Rens, Wilhelm and Rath are presented above. The combined references do not teach establishing a sheath fluid which contains a HEPES buffered medium.

However, Catt teaches that semen may be diluted in a HEPES-buffered SOF (synthetic oviduct fluid) medium and that such a fluid is suitable for maintaining the viability of spermatozoa (see, e.g., page 252 and 257). Catt also teaches that it is beneficial to sort into a medium containing a cushioning of seminal plasma to increase the viability and motility of sperm. Further, Wilhelm (page 321) does teach the use of a HEPES-buffered medium for extending equine sperm.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have further modified the method of Rens in view of Wilhelm so as to have used a HEPES-buffered medium for establishing a sheath fluid.

To have used a buffer well known to be effective for diluting and extending sperm as a sheath fluid would have been obvious to one of ordinary skill in the art. Thereby, it would have been obvious to have used a HEPES-buffered medium as the sheath fluid because Catt teaches that this is a suitable dilution medium for sperm this would have achieved the benefit of ensuring the viability and motility of the sperm.

RESPONSE TO ARGUMENTS:

In the response, Applicants traversed this rejection for the same reasons as stated above. Accordingly, the response to those arguments as presented above apply equally to the present grounds of rejection.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 138-140 and 142-145 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S.

Patent No. 7195920 in view of Rath and Wilhelm. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims

and the claims of '920 are both inclusive of methods comprising establishing a cell source, establishing a sheath fluid environment, sensing a property of viable sperm cells, discriminating between sperm cells based on a sex characteristic at a rate of at least about 1200 sorts per second, and collecting sorted sperm cells having the desired sex characteristics by collecting the sperm cells in a container in which the cells are cushioned from impact with the container. The claims of '920 are inclusive of any applying the sorting method to sperm obtained from any source and thereby are considered to encompass applying the sorting method to equine sperm. The claims of '920 also do not recite the additional step of establishing a skim milk solution into which droplets containing the sperm cells are collected. Rath (page 796) teaches collecting sex-sorted sperm into a collection media composed of TEST extender containing 2% hen egg yolk. Thus, Rath teaches collecting sperm sorted cells into a sperm extender medium. Wilhelm teaches extending equine sperm in skim milk solution containing 2% egg yolk by volume (page 322; referred to therein as SMEY). Additionally, Wilhelm teaches that SMEY extender effectively preserves equine sperm during freezing and thawing and teaches that egg yolk and skim milk may contain components which protect spermatozoa membranes (page 326). Accordingly, in view of the teachings of Rath and Wilhelm, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method claimed in '920 so as to have collected the equine sperm in the SMEY extender solution of skim milk and egg yolk in order to have sorted the sperm into a medium that helped to preserve the sperm and/or which could be used for subsequently freezing and then thawing the sorted equine

sperm. Specifically, Rath teaches that the sorted sperm are collected into a tube containing sperm extender and it would have been obvious to the ordinary artisan that alternative extenders that were known in art to be effective for preserving equine sperm, such as the skim milk extender of Wilhelm, could be present in the collection tube in order to ensure the proper collection of the sperm.

Regarding the recitation in the claims at step (j), it is considered to be a property of the resulting artificial insemination sample that it is capable of fertilizing at least one equine egg at a level not statistically different from that obtained using a typical unsorted equine artificial insemination dosage.

With respect to claim 140, the recitation of "about four percent egg yolk" is considered to encompass 2% egg yolk. Furthermore, it would have been well within the skill of the art at the time the invention was made to have modified the concentration of egg yolk in the extender solution in order to have provided the most effective concentration of egg yolk depending on the other reagents present in the extender solution.

With respect to claim 143, the claims of '920 encompass sorting at a pressure of fifty pounds per square inch.

With respect to claims 144 and 145, the claims of '920 do not recite the quantity and volume of sperm to be used in equine artificial insemination samples. However, the parameters which effect artificial insemination of equine were known in the art at the time the invention was made, it would have been obvious to one of ordinary skill in the art and well within the skill of the art to have selected an optimum quantity of sperm,

wherein said quantity would be less than 25 million and to have selected the optimum volume for the artificial insemination sample, so as to have provided the most effective sample for inseminating equine while keeping the number of sperm to be used for insemination at the lowest possible number given the constraints on how many sperm could be sorted per day and the cost of sorting. Additionally, the ordinary artisan would have recognized that the quantity of sperm and the volume of the sperm sample could be modified in order to have provided the most appropriate sperm sample depending on how the sample would be used – i.e., depending on the amount of sperm present in the original sample, whether the samples would be frozen prior to use, the number of samples to be used for insemination, and the type of insemination technique.

Accordingly, to have generated sorted sperm samples containing less than 5 or 25 million sperm or to have generated sorted sperm samples in a volume of .2 or 1 ml would have been obvious to one of ordinary skill in the art because the ordinary artisan would have recognized that the quantity of sperm and the volume of sample should be varied depending on how the sperm sample was to be further processed and / or used.

8. Claim 141 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 7195920 in view of Rath and Wilhelm, and further in view of Catt. The teachings of the claims of '920, Wilhelm and Rath are presented above. The claims of '920 do not recite establishing a sheath fluid which contains a HEPES buffered medium. However, Catt teaches that semen may be diluted in a HEPES-buffered SOF (synthetic oviduct fluid) medium and that such a fluid is suitable for maintaining the viability of spermatozoa (see, e.g., page

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252 and 257). Catt also teaches that it is beneficial to sort into a medium containing a cushioning of seminal plasma to increase the viability and motility of sperm.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have further modified the method claimed in '920 so as to have used a HEPES-buffered medium for establishing a sheath fluid because Catt teaches that this is a suitable dilution medium for sperm and thereby using HEPES-buffered medium as the sheath fluid would have achieved the benefit of ensuring the viability and motility of the sperm.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is 571-272-0747. The examiner can normally be reached on Monday-Thursday (6:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Carla Myers/

Primary Examiner, Art Unit 1634